

EXHIBIT K

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>In re</i> Continuation Patent Application of)
Michael FRANCIS, et al.) Confirmation No. 1508
Application No: 16/909,058) Group Art Unit: 1613
Filed: June 23, 2020) Examiner: SONG, Jianfeng
For: BIOPOLYMER COMPOSTIONS, SCAFFOLDS AND DEVICES) Date: January 28, 2021

DECLARATION UNDER 37 C.F.R. 1.132

United States Patent and Trademark Office
Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

I, Michael P. Francis, Ph.D., declare and state as follows:

1. I am the Chief Scientific Officer for the Applicant, Embody, Inc., and also am one of the inventors named on the above-captioned application.

2. I am a named inventor on the primary reference ("Francis"), U.S. Pub. No. US 2016/0022865 A1, which was cited by the U.S. Patent and Trademark Office ("Office"), and which is assigned on its face to LifeNet Health.

3. My professional experience includes 25 years of tissue engineering, additive manufacturing, biomaterials, genetics, extracellular matrix biology broadly, and specifically expertise in collagen and polymer chemistry. I have been involved in both discovery and development activities, including an Achilles Tendon repair device that recently was cleared by the US Food and Drug Administration. Prior to joining Applicant, I was the scientific lead at LifeNet health for orthobiologics, having invented and commercialized multiple collagen-based therapeutics for orthopedics indications.

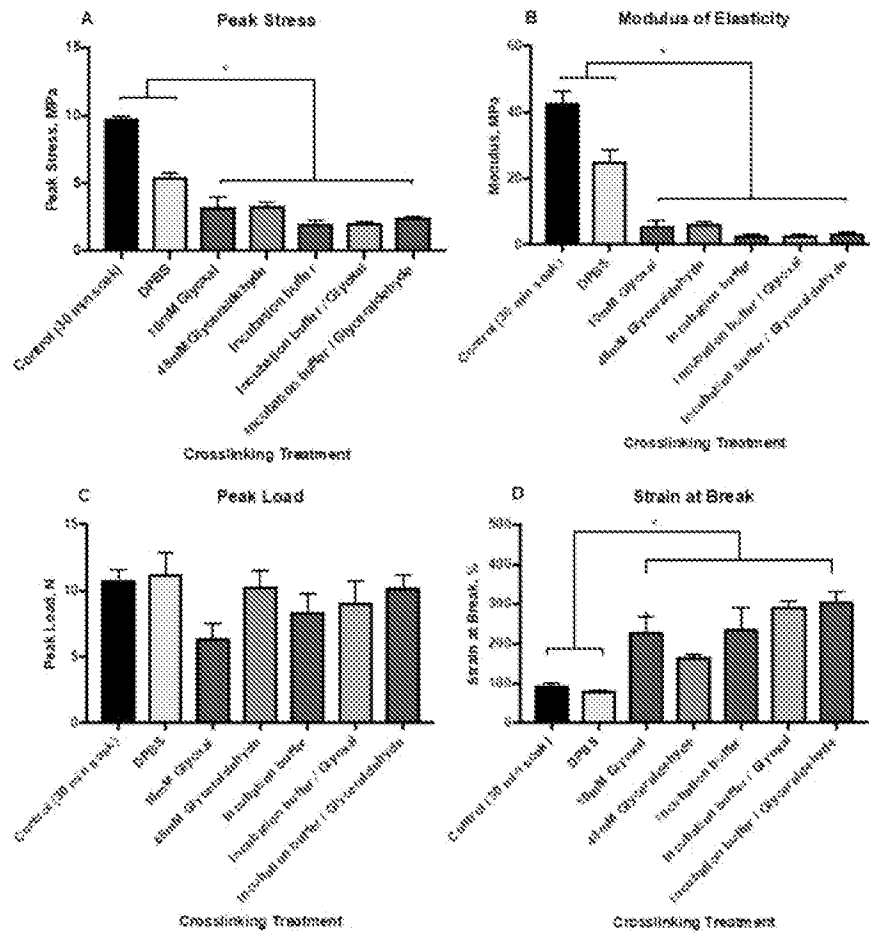
4. I am familiar with the examination record of this application in the Office. I have reviewed the Francis primary reference and the secondary reference ("Qiao"), which is a journal article by Qiao et al.,

entitled "Composition and in Vitro Evaluation of Nonwoven Type I Collagen/Poly-dllactic Acid Scaffolds for bone Regeneration", J. Funct. Biomater. 2015, 6, 667-686.

5. The following data, discussed in Paragraphs 6 and 7, below, are newly submitted for the record of this application. These data demonstrate that certain mechanical properties, particularly “peak stress” of **non-linked** collagen-PDLLA fiber blends are significantly superior when compared to such fibers that have been crosslinked with conventional aldehyde chemical agents, namely glyceraldehyde and glyoxal. For purposes of the comparison discussed in this Declaration, these chemical crosslinking agents are similar to the aldehyde glutaraldehyde, which was the crosslinking agent named in the Qiao reference (Abstract at p. 667) and mentioned in various places in the Francis reference (Para. 0060, for example). Also, the polar electrospinning solvent used to produce the scaffolds from which these data were derived is dimethylsulfoxide (DMSO)-based. For purposes of the comparison discussed in this Declaration, this solvent is similar to 1,1,1,3,3,3-hexafluoro-2-propanol (HFIP), which is the polar solvent named in the Qiao reference and mentioned in various places in the Francis reference (but referred to there as “HFP”). These data were generated by Applicant under my supervision.

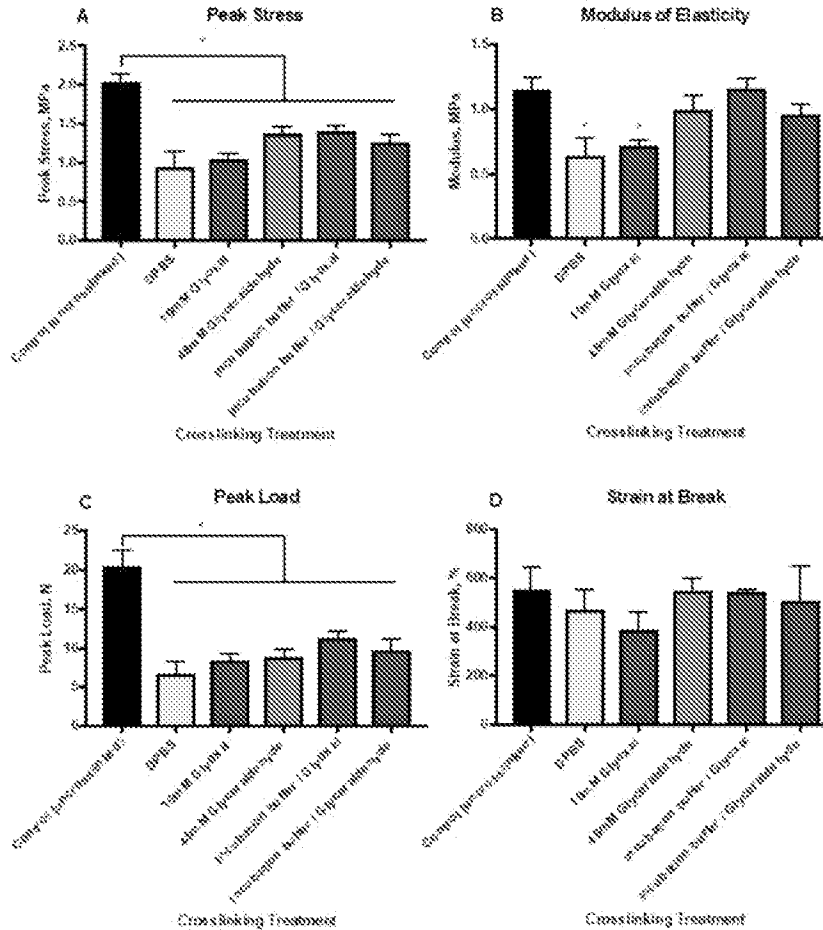
6. FIG. 1 describes the “Mechanical Properties of Crosslinked and Non-Crosslinked Scaffolds.” Electrospun constructs were treated with various compounds to test the effectiveness of crosslinking. In Fig. 1A, peak stress was measured, and all crosslinked scaffolds exhibited significantly lower mechanical strength than the control and Dulbecco’s Phosphate Buffered Saline (DPBS) groups ($p < 0.05$). In FIG. 1B, modulus of elasticity was measured, and all crosslinked scaffolds showed a lower modulus of elasticity than the controls and DPBS groups ($p < 0.05$). No significant difference was found in peak load (FIG. 1C) among the conditions tested, and all crosslinked scaffolds (FIG. 1D) exhibited a higher % strain at break than control and DPBS groups ($p < 0.05$) (data not shown).

FIG. 1



7. FIG. 2 describes “Stability of Crosslinked Scaffolds after Seven Days in Culture.” Crosslinked and uncrosslinked electrospun scaffolds were incubated in DMEM at 37°C for seven days and mechanically tested. In FIG 2A, peak stress was measured, and all crosslinked scaffolds exhibited significantly lower mechanical strength and stability after seven days in culture than the non-crosslinked control scaffold, ($p < 0.05$). In FIG 2B, peak load was measured, and all scaffolds treated with DPBS or crosslinked with glyoxal or glyceraldehyde showed a significantly lower peak strength than the non-crosslinked control scaffold), ($p < 0.05$). No significant difference was found in modulus of elasticity and strain to break peak ($p < 0.05$) (data not shown).

FIG. 2



8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application or any patent issued therefrom.

Date: January 27, 2021

Michael P. Francis

Michael P. Francis, Ph.D.